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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,158	09/15/2003	Frederic DeSavage	11669.123USC1	4053
23552	7590	07/05/2006	EXAMINER	
MERCHANT & GOULD PC			SKELDING, ZACHARY S	
P.O. BOX 2903			ART UNIT	
MINNEAPOLIS, MN 55402-0903			PAPER NUMBER	
			1644	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,158	DESAUVAGE ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 5, 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 17-22 and 26-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 23-25 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment filed May 3, 2006 has been entered.

Claims 15, 16 and 23-25 have been amended.

Claims 35 has been added.

Claims 1-35 are pending.

Claims 1-14, 17-22 and 26-34 have been withdrawn as being drawn to a non-elected invention.

Claims 15, 16, 23-25 and 35 are under consideration as they read on a method of inhibiting or attenuating the differentiation of T-cells into the Th2 subtype comprising administering an anti-TCCR antibody.

For purposes other than searching the prior art, linking claims 15 and 16 are further under consideration as they read on administering any "TCCR polypeptide agonist".

2. The rejections of record can be found in the previous Office Action, mailed November 3, 2005.

This Office Action is in response to Applicant's amendment filed May 3, 2006.

The text of those sections of Title 35 U.S.C. not included in this Office Action can be found in the previous Office Action.

3. The previous **objection** to the specification has been withdrawn in view of applicant's amendment to the specification.
4. **Claims 15, 16 and 23-25** stand rejected, and **newly added claim 35** is rejected, under **35 U.S.C. § 112, 1st paragraph** because the specification does not provide a sufficient enabling description of a method of inhibiting or attenuating the differentiation of T-cells into the Th2 subtype comprising administering an "***agonistic anti-TCCR polypeptide antibody***" or any "***TCCR polypeptide agonist***" for the reasons of record set forth in the previous Office Action.

Applicant's arguments have been considered but are not found convincing essentially for the reasons of record set forth in the previous Office Action.

Applicant argues that the data presented in the instant specification "suggest that replacement of TCCR signaling with a TCCR agonist will alleviate the exacerbated Th2 response", and

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points to copending USSN 11/275,181 ('181) and Lucas et al. (2003, PNAS 100:15047-15052) in support of their argument.

However, neither USSN 11/275,181 ('181) nor Lucas et al. (2003, PNAS 100:15047-15052) are sufficient to support applicant's contention that the claimed invention, i.e., a method of inhibiting or attenuating the differentiation of T-cells into the Th2 subtype comprising administering "*agonistic anti-TCCR polypeptide antibody*" or any "*TCCR polypeptide agonist*" is enabled.

For example, the '181 application and Lucas et al. disclose that IL-27, a ligand of the TCCR polypeptide, biases T cells toward a Th1 outcome (see entire documents, in particular page 5, 1st and 2nd paragraphs and page 15052, respectively). The '181 application also discloses that a particular anti-TCCR polypeptide monoclonal antibody called "antibody 2686" induces proliferation of Ba/F3 cells expressing human TCCR polypeptide (see pages 52-54). Ba/F3 cells are an IL-3 dependent murine pro-B cell line.

However, with respect to enabling an "*agonistic anti-TCCR polypeptide antibody*", the disclosure of the '181 application does not provide sufficient nexus between the functional activities of "antibody 2686" on Ba/F3 cells, which are *not T-cells*, and the claimed method of inhibiting or attenuating the differentiation of *T-cells* into the Th2 subtype. Lucas et al. does not disclose agonistic anti-TCCR polypeptide antibodies.

Moreover, with respect to enabling any "*TCCR polypeptide agonist*", neither Lucas et al. nor the '181 application provide sufficient support for applicant's argument that the instant application provides an enabling disclosure for the use of any "*TCCR polypeptide agonist*", for example a small molecule, for inhibiting or attenuating the differentiation of *T-cells* into the Th2 subtype.

Furthermore, with respect to enabling any "*TCCR polypeptide agonist*", applicant asserts that, "claim 15 has been amended to clarify that the claimed agonist activates the TCCR receptor and thereby induces a TCCR-mediated response...agonists of the receptor include...small molecules and the like" (see applicants response of May 3, 2006, page 11, last paragraph). However, applicant's amendment to claim 15 has no bearing on the instant rejection as amended claim 15 still reads on administering any "*TCCR polypeptide agonist*".

5. **Claims 15, 16 and 23-25** stand rejected, and **newly added claim 35** is rejected, under **35 U.S.C. § 112, 1st paragraph** as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of any "*TCCR polypeptide agonist*" for the reasons of record set forth in the previous Office Action.

Applicant's arguments have been considered but are not found convincing essentially for the reasons of record set forth in the previous Office Action and in the last paragraph of the preceeding section.

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As stated in the prior Office Action, there is insufficient written description of a method of inhibiting or attenuating the differentiation of T-cells into a Th2 subtype, comprising *any* “**TCCR polypeptide agonist**” (Claim 15). The specification does not disclose the structural and functional properties associated with *any* “**TCCR polypeptide agonist**”. Therefore, the skilled artisan cannot envision all the contemplated “**TCCR polypeptide agonists**” that could be used in a method of inhibiting or attenuating the differentiation of a T-cells into a Th2 subtype.

6. **Claims 15, 16 and 23-25** stand provisionally rejected, and **newly added claim 35** is provisionally rejected, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 16 and 23-25 of Application No. 10/088,950 for the reasons of record put forth in the prior office action.

Rejection on the basis of double patenting will be maintained until such a time that allowable subject matter is determined, at which time appropriate action by the applicant will be taken as indicated in applicant's response of May 3, 2006.

7. **Claims 15, 16 and 23-25 and 35** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description requirement**. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for “**administering to undifferentiated T-cells**” OR “**wherein said polypeptide or agonists induces a TCCR-mediated response**”.

This is a **new matter** rejection and a **New Grounds of Rejection** based on applicants amendments to the claims.

Applicant's amendment, filed May 3, 2006, does not provide sufficient direction for the written description for the above-mentioned amendment. Applicant points to page 3, lines 15-20 and Examples 3 and 12 in support of the above-mentioned amendment.

The specification as filed does not provide a sufficient written description of an “**undifferentiated T cell**” or “**induce a TCCR-mediated response**”. The specification does not provide blazemarks nor direction for claims reciting “**undifferentiated T cell**” or “**induce a TCCR-mediated response**”. This limitation, which was not clearly disclosed in the specification as-filed, changes the scope of the instant disclosure as filed. For example, “**undifferentiated T cells**” includes naïve T cells, however Example 12 discloses differentiation of “CD4+ cells”. Such limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

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Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to point out where the instant specification provides sufficient written support for “*undifferentiated T cell*” or “*induce a TCCR-mediated response*”. See MPEP 714.02 and 2163.06.

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zachary Skelding, Ph.D.
Patent Examiner
June 26, 2006

Phillip Gambel
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PRIMARY EXAMINER
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6/27/06